State of Alabama Unified Judicial System Form C-34 Rev 6/88	**SUMMONS** **-CIVIL-**	Case Number CV-06-7108

IN THE CIRCUIT **COURT OF** JEFFERSON **COUNTY**

Plaintiff WILLIAM D. McCLUSKEY **v. Defendant** MERCK & CO., INC., et al

NOTICE TO JAMES A. STEWART – D6

THE COMPLAINT WHICH IS ATTACHED TO THIS SUMMONS IS IMPORTANT AND YOU MUST TAKE IMMEDIATE ACTION TO PROTECT YOUR RIGHTS. YOU OR YOUR ATTORNEY ARE REQUIRED TO FILE THE ORIGINAL OF YOUR WRITTEN ANSWER, EITHER ADDMITTING OR DENYING EACH ALLEGATION IN THE COMPLAINT WITH THE CLERK OF THIS COURT. A COPY OF YOUR ANSWER MUST BE MAILED OR HAND DELIVERED BY YOU OR YOUR ATTORNEY TO THE PLAINTIFF OR PLAINTIFF'S ATTORNEY BENJAMIN L. LOCKLAR WHOSE ADDRESS IS BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C. POST OFFICE BOX 4160, MONTGOMERY, ALABAMA 36104.

THIS ANSWER MUST BE MAILED OR DELIVERED WITHIN 30 DAYS AFTER THIS SUMMONS AND COMPLAINT WERE DELIVERED TO YOU OR A JUDGMENT BY DEFAULT MAY BE ENTERED AGAINST YOU FOR THE MONEY OR OTHER THINGS DEMANDED IN THE COMPLAINT.

TO ANY SHERIFF OR ANY PERSON AUTHORIZED by the Alabama Rules of Civil Procedure:

☐ You are hereby commanded to serve this summons and a copy of the complaint in this action upon the defendant.

☑ Service by certified mail of this summons is initiated upon the written request of Benjamin L. Locklar pursuant to the Alabama Rules of Civil Procedure.

Date DEC 13 2006

Anne-Marie Adams
Clerk/Register By: _____

☑ Certified Mail is hereby requested.

Benjamin L Locklar
Plaintiff's/Attorney's Signature

RETURN ON SERVICE:

☐ Return receipt of certified mail received in this office on _____ (Date).

☐ I certify that I personally delivered a copy of the Summons and Complaint to _____ in _____ County, Alabama on _____ (Date).

Date _____ Server's Signature _____

Address of Server _____ Type of Process Server _____

Exhibit A-Part 1

IN THE CIRCUIT COURT OF JEFFERSON COUNTY, ALABAMA

WILLIAM D. MCCLUSKEY, as Surviving Spouse and as Personal Representative of the Estate of MARY L. MCCLUSKEY, deceased,	*	
PLAINTIFF,	*	CV2006071108
v.	*	**CASE NO.** _____
MERCK & CO., INC., a foreign Corporation; PFIZER INC., a Delaware Corporation; PHARMACIA CORPORATION, a Delaware Corporation; MONSANTO COMPANY, a Delaware Corporation; G.D. SEARLE, LLC, a Delaware Corporation; JAMES A. STEWART, an Individual; ANNA LEIGH WEBB, an Individual; CEDRIC D. ANDERSON, an Individual; TRAVIS TAYLOR, an Individual; ROBERT VANDELUNE, an Individual; and fictitious Defendants A, B, C & D, being those persons firms or Corporations whose fraud, scheme to defraud, and/or other wrongful conduct caused or contributed to the Plaintiff's injuries and damages, and whose true names and identities are presently unknown to Plaintiff, but will be substituted by amendment when ascertained,	*	
DEFENDANTS.	*	

COMPLAINT

COMES NOW, Plaintiff, William D. McCluskey, as surviving spouse and as personal representative of the Estate of Mary L. McCluskey, by and through the undersigned counsel, and files his Complaint and cause of action against the Defendants state as follows:

Exhibit A-Part 1

PARTIES, JURISDICTION AND VENUE

1. Plaintiff William D. McCluskey, is over the age of nineteen (19) years and is a resident of Jefferson County, Alabama. Mary McCluskey at the time of her death was a resident of Jefferson County, Alabama. Beginning on or about January 3, 2002, and continuing through approximately December 31, 2004, Mary McCluskey, deceased, took the prescription drugs VIOXX® (Rofecoxib) and CELEBREX® manufactured, marketed and sold by Merck & Co., Inc. and Pfizer, Inc. On or about January 14, 2005, Mary McCluskey suffered a cardiac arrest and was taken to the Medical Center Jefferson Hospital emergency room where she died. Mary McCluskey's use of VIOXX® and CELEBREX® were a substantial factor in causing her injuries and death.

2. Defendant, Merck and Co., Inc. (hereafter referred to as "Merck"), is a New Jersey corporation with its principal place of business in New Jersey. At all times material hereto, Merck was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, anti-inflammatory and other drugs, including VIOXX®. Defendant, Merck, at all times relevant hereto, was a foreign corporation, duly licensed and authorized to do business in the State of Alabama and has designated Corporation Process Company, 2000 Interstate Park Drive, Suite 204, Montgomery, Alabama 36109 as its registered agent for service of process.

3. Defendant, Pfizer, Inc. (hereafter referred to as "Pfizer"), is a Delaware corporation with its principal place of business in New York. At all times material hereto, Pfizer was engaged in the business of testing, developing, manufacturing, labeling,

Exhibit A-Part 1

marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, anti-inflammatory and other drugs, including CELEBREX®. Defendant, Pfizer, is a Delaware corporation with its principal place of business in New York. At all times relevant hereto, Pfizer was in the business of marketing, selling and distributing the pharmaceutical product CELEBREX®. Defendant Pfizer is licensed and registered to do business in the State of Alabama and may be served through its registered agent at: Pfizer, Inc., c/o The Corporation Company, 2000 Interstate Park Drive, Suite 204, Montgomery, Alabama 36109.

4. Defendant Pharmacia Corporation (hereinafter "Pharmacia") is a Delaware Corporation with its principal place of business in New Jersey. At all times relevant to this action, Pharmacia was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product CELEBREX®. Defendant Pharmacia is licensed and registered to do business in the State of Alabama. Defendant Pharmacia can be served through its registered agent at: Pharmacia Corporation, c/o The Corporation Company, 2000 Interstate Park Drive, Suite 204, Montgomery, Alabama 36109.

5. Defendant Monsanto Company (hereinafter "Monsanto") was the parent corporation of Pharmacia and is a Delaware Corporation. At all times relevant hereto, Monsanto, through its subsidiary companies, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product CELEBREX®. Defendant Monsanto is licensed and registered to do business in the State of Alabama. Defendant Monsanto can be served through its registered agent at: Monsanto Company,

Exhibit A-Part 1

c/o Lawyers Incorporating Service Inc., 150 South Perry Street, Montgomery, Alabama 36104.

6. Defendant G. D. Searle LLC (hereinafter "Searle") was a subsidiary of Pharmacia Corporation and is upon information, knowledge and belief an Illinois Corporation. At all times relevant hereto, Searle, as a subsidiary of Pharmacia Corporation, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product CELEBREX®. Defendant Searle is licensed and registered to do business in the State of Alabama. Defendant Searle can be served through its registered agent at: G. D. Searle, LLC, c/o CT Corporation System, 208 South LaSalle Street, Suite 814, Chicago, Illinois 60604.

7. Defendants, James A. Stewart, Anna Leigh Webb, Cedric D. Anderson, Travis Taylor, Robert Vandelune, and fictitious defendants A, B, C, and D, are all parties representing drug sales representatives, supervisors or "detail persons" who, on behalf of Merck and Pfizer, marketed and promoted VIOXX®, BEXTRA® and CELEBREX® in Jefferson County, Alabama, to the health care provider(s) treating Mary McCluskey, and prescribing or otherwise supplying VIOXX® and CELEBREX® to Mary McCluskey. On information and belief, at all times material hereto, the Defendants, James A. Stewart, Anna Leigh Webb, Cedric D. Anderson, Travis Taylor and Robert Vandelune are or were residents of the State of Alabama and can be served at the following address:

a. James A. Stewart
1832 Seneca Road
Birmingham, Alabama 35216

b. Anna Leigh Webb
1093 Eagle Valley Drive
Birmingham, Alabama 35242

Exhibit A-Part 1

c. Cedric D. Anderson
1050 Williams Trace
Birmingham, Alabama 35242

d. Travis Taylor
8718 Vintage Way
Montgomery, Alabama 36616

e. Robert Vandelune
1206 Rampart Road
Dothan, Alabama 36303

8. Fictitious Defendants A, B, C & D, are other legal persons (including retailers, pharmacies, sales representatives and manufacturers) who manufactured, labeled, advertised, marketed, promoted, sold and/or distributed VIOXX® and CELEBREX® in the State of Alabama, or who detailed, discussed with, or provided materials to physicians and healthcare providers in the State of Alabama.

9. When the word "Defendants" is used herein, it is meant to refer to all real and fictitious Defendants mentioned in the style of this Complaint, all of whom are jointly and severally liable to Plaintiff for Plaintiff's decedent's injuries and death.

10. At all times material to this complaint, each Defendant acted as an agent for each of the other Defendants, within the course and scope of the agency, regarding the acts and omissions alleged herein, and are therefore jointly and severally liable to Plaintiff for Plaintiff's decedent's injuries and death.

FACTUAL BACKGROUND

Properties of COX Inhibitors

11. VIOXX® and CELEBREX® are prescription drugs designed and used to treat pain and inflammation. As discussed below, VIOXX® and CELEBREX® are COX-2 selective non-steroidal anti-inflammatory agents ("NSAID").

12. NSAIDs were developed in the 1960's and 1970's, and prescribed to provide relief of pain and inflammation. They were widely used by the 1990's, especially by older people suffering from osteoarthritis and rheumatoid arthritis. Epidemiological studies in the 1980's demonstrated that long term use of NSAID's increased the risk of gastrointestinal ("GI") problems by 4-6 times, with the risk being more pronounced in the elderly. As a result, researchers and pharmaceutical companies began seeking alternative treatments with fewer gastrointestinal side effects.

13. NSAID's work by inhibiting the action of the cyclooxygenase (COX) enzyme which is involved in the production of prostaglandins, thereby reducing inflammation and the associated pain. Research into the causes of gastrointestinal toxicity showed that prostaglandins also play a role in protecting the stomach lining from the effects of gastric acid.

14. In 1989, it was postulated that there were two forms of the COX enzyme: COX-1 and COX-2. It was believed that COX-2 played a role in the release of prostaglandin from inflammatory sites, while COX-1 helped maintain the integrity of the GI tract. Typical NSAIDs inhibit both forms of the COX enzyme. It was theorized that a drug which inhibited only COX-2 would reduce inflammation without adverse GI effects. This class of drugs is known as the coxibs.

15. COX-2 is involved in more than the inflammatory process. It plays a role in normal renal function, reproductive biology and neurological functioning. COX-2 also

Exhibit A-Part 1

plays a role in maintaining normal functioning of the vascular endothelium and in the production of prostacyclin ("PGI_2").

16. COX-2 is associated with the production of PGI_2 by the vascular endothelium. PGI_2 inhibits platelet aggregation (clotting) and is a vasodilator. In contrast, COX-1 is associated with the production of thromboxane A_2 ("TXA_2") by platelets. TXA_2 is a potent platelet aggregator and vasoconstrictor. Under normal circumstances PGI_2 and TXA_2 have offsetting effects resulting in a homeostatic balance within the body.

17. NSAID's are non-selective COX inhibitors that inhibit both COX-1 and COX-2, thereby inhibiting production of both PGI_2 and TXA_2, and maintaining a rough balance between the two. Selectively inhibiting COX-2 upsets the natural balance between PGI_2 and TXA_2 by inhibiting primarily PGI_2, thereby giving free rein to TXA_2's clotting and vasoconstriction properties.

18. COX -2 also helps maintain the normal functioning of the vascular endothelium where not only PGI_2 but other anti-coagulants such as nitric oxide, thrombomodulin, heparin sulfates and t-PA are produced. COX-2 inhibition therefore blocks redundancies in the vascular system by suppressing production of these other anti-coagulants by the vascular endothelium.

19. This impact on endothelial function is especially important given that many likely users of COX-2 inhibitors will have pre-existing or pre-disposing factors for cardiovascular risks, including some degree of atherosclerotic plaque which damages the vascular endothelium. A damaged vascular endothelium causes an imbalanced pro-thrombotic state because the damaged endothelium contributes to narrowed arteries and

also produces less PGI_2 and other anti-coagulants which would otherwise inhibit platelet aggregation.

20. Many users of COX-2 inhibitors are at a heightened risk and even more susceptible to the pro-thrombotic effects of selective COX-2 inhibition.

21 With selective COX-2 inhibition, there is no corresponding suppression of the platelet aggregation and vasoconstriction effects of TXA_2.

The VIOXX® Timeline

22. On or about November 23, 1998, Merck submitted to the Food and Drug Administration ("FDA") a New Drug Application ("NDA") for Rofecoxib (VIOXX®).

23. Before submittal of its NDA, Merck knew that selective COX-2 inhibition could be pro-thrombotic and dangerous to the potential users of VIOXX®. Merck actively contrived to conceal and minimize this fact for fear that it would "kill" the drug.

24. Before submittal of its NDA, Merck declined to study the cardiovascular effects of COX-2 inhibition in the patients expected to use VIOXX®, even though Merck was aware that many users of VIOXX® would already be at risk of serious adverse cardiovascular events. Merck never advised health care providers or patients of its failure to conduct such studies.

25. Before approval of its NDA, Merck was aware that other researchers had also confirmed in both human and animal studies the likelihood of serious cardiovascular risk with the use of COX-2 inhibitors and that further trials were necessary to determine whether a COX-2 inhibitor would be both efficacious and safe in its intended population.

Exhibit A-Part 1

26. On or about May 17, 1999, the FDA safety review of the Merck NDA for VIOXX® also noted Merck's inability to provide an answer to the actual risk of adverse cardiovascular and thromboembolic events for patients on VIOXX®.

27. Merck has never conducted any testing meant to determine the risk of cardiovascular and thromboembolic events in the intended patient population of VIOXX® users.

28. On or about May 20, 1999, the FDA approved VIOXX®.

29. Merck immediately launched aggressive advertising and public relations campaigns to promote VIOXX®.

30. On or about June 22, 1999, Merck hired Peter Holt, M.D. to promote the use of VIOXX® to health care providers.

31. The FDA later found that parts of Dr. Holt's presentations promoting the use of VIOXX® were false or misleading.

32. On or about July 16, 1999, the FDA issued a warning letter to Merck regarding VIOXX® direct to consumer ("DTC") advertising.

33. On or about January 1, 1999, Merck began the VIOXX Gastrointestinal Outcomes Research ("VIGOR") trial to substantiate a gastrointestinal safety claim for the drug.

34. On or about November 18, 1999, the VIGOR Data Safety Monitoring Board expressed concern about the "excess deaths and cardiovascular events" in the group of study participants taking VIOXX®.

35. On or about December 16, 1999, the FDA sent Merck a letter noting that several promotional pieces were false or misleading because they misrepresented the

safety profile of VIOXX®, contained unsubstantiated comparative claims and promoted unapproved uses.

36. On or about December 1999, Merck began patient screening for the APPROVe trial, a study to evaluate whether VIOXX® prevented the recurrence of colon polyps.

37. On or about March 2000, Merck revealed the initial VIGOR results showing that patients using VIOXX® had double the rate of serious cardiovascular events than those on the comparator drug, Naproxen (a non-selective NSAID). The data also showed a four-fold increase in heart attack risk. When the complete data was reanalyzed, the actual increase in relative risk of a heart attack was 5.04, compared to a relative risk of 1.0 in the participants taking Naproxen rather than VIOXX®. The relative risk of a serious cardiovascular event, which included heart attacks, strokes, sudden death and unstable angina, was 2.3.

38. Merck acknowledged internally that the VIGOR results raised serious questions regarding the safety of VIOXX® for its intended users. Nevertheless, Merck set out to minimize, obfuscate and misrepresent the results of the VIGOR study in order to conceal the cardiovascular risks attributable to VIOXX®.

39. During this time, Merck continued to be aware of the adverse cardiovascular effects associated with the use of VIOXX®. Merck also became aware of studies indicating that the COX-2 enzyme selectively suppressed by VIOXX® is cardio-protective.

40. Once again, Merck decided not to conduct a study designed to determine the extent of cardiovascular risks associated with VIOXX®.

41. Instead, Merck continued to dispute these and other studies indicating increased cardiovascular risks associated with VIOXX® and the cardio-protective effects of the COX-2 enzyme.

42. On or about November 2000, Merck published the VIGOR results in the New England Journal of Medicine and downplayed the cardiovascular risks, suggesting that the drug presented no risk to those with healthy hearts and omitting detailed information about other cardiovascular complications like strokes. The article prominently discussed the reduction of stomach bleeds in patients taking VIOXX®, but did not mention that patients on VIOXX® had more serious adverse events and more hospitalizations than patients on Naproxen. The true rates for cardiovascular thrombotic adverse events, hypertension and congestive heart failure – all of which were higher in the VIOXX® group - were not disclosed.

43. On or about February 8, 2001, an FDA Advisory Panel recommended that the VIOXX® labeling be changed to reflect the cardiovascular risks.

44. On or about August 29, 2001, the Journal of the American Medical Association published a peer reviewed study by the Cleveland Clinic Foundation which conducted a meta-analysis of several clinical trials, including the VIGOR trial. The authors concluded that the VIGOR results showed a 2.2 times greater risk of a serious cardiovascular event in those taking VIOXX® as compared to Naproxen. The relative risk between VIOXX® and Naproxen among aspirin-indicated patients (i.e., those already at some cardiac risk) was 4.89. The authors theorized that COX-2 inhibitors "by decreasing PGI_2 production may tip the natural balance between prothrombotic thromboxane A_2 and antithrombotic PGI_2, potentially leading to an increase in thrombotic

cardiovascular events." The authors concluded with the observation: "Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents." Mukherjee, D., et al., *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, J. Amer. Med. Assn. 286:8, 954, 957, August 22/29, 2001.

45. Two of the Cleveland Clinic study authors, Drs. Topol and Nissen, were lobbied by Merck to temper their criticisms prior to publication.

46. On or about September 17, 2001, the FDA sent a Warning Letter to Merck regarding promotional audio conferences conducted by Dr. Holt, a Merck press release regarding the safety profile of VIOXX®, and oral representations made by Merck sales representatives to promote the sale of VIOXX®. The letter began:

> You have engaged in a promotional campaign for VIOXX that minimizes the potentially serious cardiovascular findings that were observed in the VIOXX Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for VIOXX.

47. The FDA further stated that Dr. Holt's assertions "minimize the potentially serious MI risk that may be associated with VIOXX® therapy."

48. The FDA noted in the letter that Merck's "misrepresentation of the safety profile for VIOXX® is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for VIOXX® that also misrepresented VIOXX®'s safety profile."

49. In the Warning Letter, the FDA also noted repeated misrepresentations of the actual VIGOR study results. For example, Dr. Holt had asserted that the overall safety

profile of COX-2 inhibitors, including VIOXX®, was safer than that of other NSAIDs. The FDA noted that "such an advantage has not been demonstrated," and further stated:

> In fact, in the VIGOR study the incidence of serious adverse events was **higher** in the VIOXX treatment group than in the naproxen treatment group (9.3% and 7.8% for VIOXX and naproxen, respectively). The results of safety analyses that were pre-specified in the protocol for the VIGOR trial, such as CHF related adverse events and discontinuations due to edema-related adverse events, hepatic-related adverse events, hypertension-related adverse events, and renal-related adverse events were all numerically higher (in some cases statistically significantly higher) in the VIOXX treatment group than in the naproxen treatment group.

50. The FDA criticized Merck for other misleading actions:

> We have identified a Merck press release entitled, "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX," dated May 22, 2001, that is also false or misleading for similar reasons stated above. Additionally, your claim in the press release that VIOXX has a "favorable cardiovascular safety profile," is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen.

51. Finally, the FDA determined that Merck sales representatives had engaged in false or misleading promotional activities.

52. Because of the seriousness of the violations and the fact that Merck had previously been notified of similar violations, FDA required Merck to issue a "Dear Healthcare Provider" letter correcting the false or misleading impressions and information.

53. Throughout this time period, a number of healthcare organizations asked Merck to test whether VIOXX® increased the risk of heart attack and stroke.

54. On or about December 15, 2001, the FDA reviewed a Supplemental NDA ("SNDA") to approve VIOXX® for the treatment of rheumatoid arthritis. After

evaluating VIGOR and other studies, the FDA reviewer concluded that "the potential advantage of decreasing the risk of complicated [GI adverse events] was counterbalanced by the increased rate of developing serious non-GI events (particularly cardiovascular events)."

55. By 2003 Merck still had not conducted a study specifically designed to assess cardiac and thrombotic risks associated with VIOXX®. The need for such a study was especially great given inherent limitations in the FDA's Adverse Event Reporting System. That system is useful for identifying unusual events, but practically worthless for common events such as heart attack and stroke.

56. Independent researchers continued to conclude that the use of VIOXX® and other COX-2 inhibitors lead to increased vascular and thrombotic events and that their poor safety performance could not be excused by the attempted explanations of Merck.

57. On or about April 11, 2002, over two years after the initial VIGOR results became available and despite much resistance from Merck, the FDA ordered new labeling for VIOXX®. Merck was allowed to place the revised GI labeling up front, followed by a graphical presentation of the cardiovascular data. The revised label urged doctors to use caution in prescribing VIOXX® for patients with ischemic heart disease. The label also stated that VIOXX® 50 mg. was not recommended for chronic use and that the 25 mg. dose was associated with a higher risk of hypertension compared to Naproxen. The cardiac data was presented in the "Precautions" section, not in the warnings. There was no Black Box warning. Despite the findings of other researchers,

Merck stated in its label that the significance of the cardiovascular findings seen in VIGOR and other studies was unknown.

58. On or about September 2002, Merck began the MEDAL study, which included over 23,000 patients and was specifically designed to assess the cardiovascular safety of ARCOXIA®, Merck's planned successor to VIOXX®. No comparable study was ever done by Merck to evaluate VIOXX®.

59. Both independent researchers and studies funded by Merck continued to show the increased cardiovascular risk of VIOXX®. Merck nevertheless continued to ignore adverse findings and attempted to obstruct and minimize the import of these studies.

60. On or about August 25, 2004, Dr. David Graham of the FDA presented preliminary research findings at a conference in Bordeaux, France. Dr. Graham had conducted a study prompted by the VIGOR results and funded by the FDA intended to assess cardiac risk in patients taking VIOXX®. Based on his analysis, Graham concluded that VIOXX® was responsible for over 27,700 heart attacks and sudden coronary deaths between 1999 and 2003; 14,845 of these adverse events were at doses less than or equal to 25 mg. and 12,940 at higher doses. Graham has since increased that estimate to almost 140,000 heart attacks and sudden coronary deaths.

61. On or about August 27, 2004, Merck issued a press release stating that it "strongly disagrees" with Graham's findings and "stands behind the efficacy and safety, including cardiovascular safety, of VIOXX." On or about the same day, the APPROVe Data Safety Monitoring Board (the colon polyp prevention study begun on or about

December 1999) confirmed that VIOXX® tripled cardiac risk, and more than doubled the relative risk for a cerebrovascular event (2.33).

62. On or about September 27, 2004, Merck advised the FDA that data from the APPROVe trial indicated a tripled risk of heart attack.

63. On or about September 30, 2004, Merck publicly announced that it was pulling VIOXX® from the market.

64. On or about November 5, 2004, The Lancet published online a cumulative meta-analysis of earlier VIOXX® clinical trial data, in which the authors concluded that VIOXX® should have been withdrawn from the market several years earlier. The authors asserted that "an increased risk of myocardial infarction was evident from 2000 onwards," and that by the end of 2000, "the effect was both substantial and unlikely to be a chance finding." The authors further rejected Merck's efforts "to explain [away] the findings of VIGOR." The authors also commented on the exclusion criteria of most of the trials, noting that patients with a history of cardiovascular disease routinely were excluded. Noting that many such patients were likely taking the drug, the researchers pointed out that the risk of MI in this already at risk population was over eight (8) times higher. Merck never attempted to test the cardiovascular risks of VIOXX® in this population, even though it knew that many patients taking the drug were at increased cardiovascular risk.

65. Despite a known risk potential, repeated calls for study and results from the VIGOR and other trials, Merck recklessly and willfully failed to conduct adequate studies to establish the safety of VIOXX®.

66. Merck never disclosed on its warning labels that such testing had not been performed, thereby fraudulently inducing health care providers and patients alike to use VIOXX® under the false assumption that it had been sufficiently tested.

67. By the end of 1999, less than 5 million prescriptions had been written for VIOXX® according to the Merck Annual Report. By the time the drug was pulled in 2004, over 105 million prescriptions had been written.

68. VIOXX® was only tested and approved for up to five days of use at the 50mg dosage.

The CELEBREX® Timeline

69. On or about June 29, 1998, G.D. Searle & Co. ("Searle") submitted a New Drug Application ("NDA") for BEXTRA® and CELEBREX®. The FDA granted approval on December 31, 1998. Thereafter, BEXTRA® and CELEBREX® were jointly marketed by Searle and Pfizer. On or about March 2001, Searle was acquired by Pharmacia Corp. a/k/a Pharmacia & Upjohn, Inc. ("Pharmacia"). On or about July 2002, Pfizer and Pharmacia signed an agreement for the acquisition of Pharmacia by Pfizer. The Acquisition was completed on or about April 2003. As used herein, "Pfizer" includes each of these entities as the date and context may require.

70. Following FDA approval, Pfizer launched an aggressive advertising and public relations campaign to promote BEXTRA® and CELEBREX®.

71. Pfizer never conducted any testing where cardiovascular and thromboembolic events were the primary endpoints.

72. Before submittal of the BEXTRA® and CELEBREX® NDA, Pfizer knew that selective COX-2 inhibition could be pro-thrombotic and dangerous to the potential

users of CELEBREX®. Pfizer actively contrived to conceal and minimize this fact for fear that it would hurt sales of the drugs.

73. Before submittal of the BEXTRA® and CELEBREX® NDA, Pfizer declined to study the cardiovascular effects of COX-2 inhibition in the patients expected to use BEXTRA® and CELEBREX®, even though Pfizer was aware that many users of BEXTRA® and CELEBREX® would already be at risk of serious adverse cardiovascular events. Pfizer never advised health care providers or patients of its failure to conduct such studies.

74. Before approval of the BEXTRA® and CELEBREX® NDA, Pfizer was aware that other researchers had also confirmed in both human and animal studies the likelihood of serious cardiovascular risk with the use of COX-2 inhibitors and that further trials were necessary to determine whether a COX-2 inhibitor would be both efficacious and safe in its intended population.

75. The FDA safety review of the NDA for Pfizer's second COX-2 inhibitor, BEXTRA®, noted Pfizer's inability to provide an answer to the actual risk of adverse cardiovascular and thromboembolic events for patients on BEXTRA®.

76. Pfizer has never conducted any testing meant to determine the risk of cardiovascular and thromboembolic events in the intended patient population of BEXTRA® and/or CELEBREX® users.

77. On or about January 1, 1999, Merck began the VIOXX® Gastrointestinal Outcomes Research ("VIGOR") trial to substantiate a gastrointestinal safety claim for its COX-2 drug, VIOXX®.

78. On or about November 18, 1999, the VIGOR Data Safety Monitoring Board expressed concern about the "excess deaths and cardiovascular events" in the group of study participants taking VIOXX®.

79. On or about March 2000, Merck revealed the initial VIGOR results showing that patients using VIOXX® had double the rate of serious cardiovascular events than those on the comparator drug, Naproxen (a non-selective NSAID). The data also showed a four-fold increase in heart attack risk. When the complete data was reanalyzed, the actual increase in relative risk of a heart attack was 5.04, compared to a relative risk of 1.0 in the participants taking Naproxen rather than VIOXX®. The relative risk of a serious cardiovascular event, which included heart attacks, strokes, sudden death and unstable angina, was 2.3.

80. During this time, Pfizer continued to be aware of the adverse cardiovascular effects associated with the use of BEXTRA® and CELEBREX®. Pfizer also became aware of studies indicating that the COX-2 enzyme selectively suppressed by BEXTRA® and CELEBREX® is cardio-protective.

81. Once again, Pfizer decided not to conduct a study designed to determine the extent of cardiovascular risks associated with BEXTRA® and CELEBREX®.

82. Instead, Pfizer continued to dispute these and other studies indicating increased cardiovascular risks associated with BEXTRA® and CELEBREX® and the cardio-protective effects of the COX-2 enzyme.

83. On or about November 2000, the VIGOR results were published in the New England Journal of Medicine.

84. On or about August 29, 2001, the Journal of the American Medical Association published a peer reviewed study by the Cleveland Clinic Foundation which conducted a meta-analysis of several clinical trials, including the VIGOR trial. The authors concluded that the VIGOR results showed a 2.2 times greater risk of a serious cardiovascular event in those taking VIOXX® as compared to Naproxen. The relative risk between VIOXX® and Naproxen among aspirin-indicated patients (i.e., those already at some cardiac risk) was 4.89. The authors theorized that COX-2 inhibitors "by decreasing PGI_2 production may tip the natural balance between prothrombotic thromboxane A_2 and antithrombotic PGI_2, potentially leading to an increase in thrombotic cardiovascular events." The authors concluded with the observation: "Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents." Mukherjee, D., et al., *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, J. Amer. Med. Assn. 286:8, 954, 957, August 22/29, 2001.

85. Two of the Cleveland Clinic study authors, Drs. Topol and Nissen, claim they were lobbied by the manufacturers, Merck and Pfizer, to temper their criticisms prior to publication, and further stated that they had tried unsuccessfully to get the manufacturers to launch new clinical studies of the possible cardiac risks.

86. By 2003 Pfizer still had not conducted a study specifically designed to assess cardiac and thrombotic risks associated with BEXTRA® and CELEBREX®. The need for such a study was especially great given inherent limitations in the FDA's Adverse Event Reporting System. That system is useful for identifying unusual events, but practically worthless for common events such as heart attack and stroke.

87. Independent researchers continued to conclude that the use of BEXTRA® and CELEBREX® and other COX-2 inhibitors lead to increased vascular and thrombotic events and that their poor safety performance could not be excused by the attempted explanations of Pfizer and other manufacturers.

88. Both independent researchers and studies funded by COX-2 manufacturers continued to show the increased cardiovascular risk of COX-2 inhibitors, including BEXTRA® and CELEBREX®. Pfizer nevertheless continued to ignore adverse findings and attempted to obstruct and minimize the import of these studies.

89. On or about September 30, 2004, Merck publicly announced that it was pulling its COX-2 inhibitor, VIOXX®, from the market because data from a clinical trial indicated a tripled risk of heart attack.

90. On or about January 10, 2005, the FDA sent a nine page letter to Pfizer, warning that Pfizer's promotion of BEXTRA® and CELEBREX® was false and misleading and demanding corrective action.

91. On or about January 19, 2005, the Journal of the American Medical Association published an editorial by Eric Topol, discussing the need, as early as 2000, for clinical trials assessing the cardiovascular safety of VIOXX®, BEXTRA® and CELEBREX®. Topol, E., *Arthritis Medicines and Cardiovascular Events—"House of Coxibs"*, Journal of the American Medical Association, Vol. 293, No. 3 January 19, 2005.

92. Despite a known risk potential, repeated calls for study and results from the VIGOR and other trials, Pfizer recklessly and willfully failed to conduct adequate studies to establish the safety of BEXTRA® and CELEBREX®.

Exhibit A-Part 1

93. Pfizer never disclosed on its warning labels that such testing had not been performed, thereby fraudulently inducing health care providers and patients alike to use BEXTRA® and CELEBREX® under the false assumption that they had been sufficiently tested.

Fraudulent Concealment, Tolling and Estoppel

94. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial by Merck and Pfizer of the facts as alleged herein.

95. Decedent, Mary McCluskey was kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on her part.

96. Mary McCluskey could not reasonably have discovered the dangerous nature of and unreasonable adverse side effects associated with VIOXX® and CELEBREX® before the publicity surrounding the drugs. Merck and Pfizer should be estopped from relying on any statute of limitations defense because Merck and Pfizer are and were under a continuing duty to disclose the true character, quality, and nature of VIOXX® and CELEBREX® to decedent Mary McCluskey and failed to do so.

97. Plaintiff William McCluskey did not have any factual basis to be aware of his claims asserted herein until less than one year before the filing of this action.

98. Merck and Pfizer should be estopped from asserting the affirmative defense that any of decedent, Mary McCluskey's health care providers were learned intermediaries since Merck and Pfizer actively misrepresented and concealed vital safety information regarding the cardiovascular risks of VIOXX® and CELEBREX®.

CAUSES OF ACTION

COUNT I – STRICT LIABILITY AND/OR NEGLIGENCE PER SE
(Against Merck and Pfizer)
Restatement of Torts (Second) §402A
or
Restatement of Torts (Third): Prod. Liab. §6

99. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

100. VIOXX® and CELEBREX® are sold by Merck and Pfizer and were defective and unreasonably dangerous to consumers, including Mary McCluskey.

101. VIOXX® and CELEBREX® were expected to reach, and did reach, prescribing health care providers and consumers throughout the United States, including Mary McCluskey, without substantial change in the condition in which they were originally sold by Merck and Pfizer.

102. VIOXX® and CELEBREX® were defective and unreasonably dangerous at the time they were placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. VIOXX® and CELEBREX® had unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Mary McCluskey to risks which exceeded any benefits of the drugs;

b. VIOXX® and CELEBREX® were defective in design and formulation, because making use of the drugs was more dangerous than an ordinary consumer would expect and Merck and Pfizer failed to adequately warn of the risks associated with the use of said drugs;

c. Merck and Pfizer failed to conduct adequate pre- and post-clinical testing and research to determine the safety of VIOXX® and CELEBREX® despite overwhelming evidence of the need for such testing and research; and

Exhibit A-Part 1

d. The benefits of using VIOXX® and CELEBREX® were outweighed by the risks of a serious cardiovascular adverse event.

The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey and for which Merck and Pfizer are legally responsible.

COUNT II - NEGLIGENCE
(Against Merck and Pfizer)

103. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

104. At all relevant times, Merck and Pfizer had a duty to exercise reasonable care to properly prepare, design, research, develop, test, manufacture, inspect, label, market, promote, and sell VIOXX® and CELEBREX®, including a duty to insure that users did not suffer from unreasonable, dangerous or untoward adverse side effects.

105. At all relevant times, Merck and Pfizer owed a duty to properly warn consumers and their health care providers of the risks, dangers, and adverse side effects of VIOXX® and CELEBREX®.

106. Merck and Pfizer failed to exercise ordinary care in the preparation, design, research, development, testing, manufacturing, inspection, labeling, marketing, promotion, and selling of VIOXX® and CELEBREX®.

107. Merck and Pfizer knew, or in the exercise of reasonable care, should have known, that VIOXX® and CELEBREX® were likely to cause injury to a significant number of those taking the drugs if Merck and Pfizer failed to exercise ordinary care.

108. Merck and Pfizer were negligent in the preparation, design, research, development, testing, manufacturing, inspection, labeling, marketing, promotion, and selling of VIOXX® and CELEBREX® in that they:

a. Developed drugs with known potential to increase cardiovascular risk, which risks were not outweighed by any potential benefit;

b. Failed to adequately test pre-market to determine actual potential extent of adverse cardiovascular events;

c. Failed to accurately and completely report known risks of VIOXX® and CELEBREX® to the FDA;

d. Failed to fully and completely inform prescribers and the public about known risks of VIOXX® and CELEBREX®;

e. Overstated the benefits of VIOXX® and CELEBREX® relative to other safer drugs, to the FDA, prescribers, and consumers.

f. Despite direct knowledge that they were indicated and required, Merck and Pfizer refused to conduct any studies designed to determine the extent of the actual potential of adverse cardiovascular events.

g. Made no meaningful effort to report actual adverse events to the FDA, or to inform prescribers and consumers of the same;

h. Minimized, attempted to conceal and actively concealed information as it became available about the adverse cardiovascular events attributable to VIOXX® and CELEBREX®; and

i. Were otherwise careless and negligent.

109. Despite the fact that Merck and Pfizer knew or should have known that VIOXX® and CELEBREX® caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Merck and Pfizer continued to promote and market said drugs to consumers, including Mary McCluskey, when safer and more effective treatments were available.

Exhibit A-Part 1

110. Merck and Pfizer knew or should have known that consumers such as Mary McCluskey would foreseeably suffer injury and/or death as a result of their failure to exercise ordinary care as described herein.

111. The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey and for which Merck and Pfizer are legally responsible.

COUNT III – FAILURE TO WARN
(Against Merck and Pfizer)
Restatement of Torts (Second) § 388
or
Restatement of Torts (Third): Prod. Liab. §6

112. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

113. Merck and Pfizer had a continuing duty to warn the prescribing health care providers and users of VIOXX® and CELEBREX® of the risks and benefits associated with said drugs.

114. VIOXX® and CELEBREX® were defective and unreasonably dangerous when they left the possession of Merck and Pfizer because:

a. The labeling was misleading regarding the purported risks and benefits associated with said drugs; and,

b. Their labeling was inadequate to alert prescribers and consumers, such as Mary McCluskey, to the dangerous risks and adverse cardiovascular events associated with said drugs.

115. Merck and Pfizer, as manufacturers of pharmaceutical medications, are held to the level of knowledge of an expert in the field.

116. The warnings that were given by Merck and Pfizer to the prescribers and users of VIOXX® and CELEBREX® were defective in that they misrepresented what

Merck and Pfizer knew, or should have known, and were not adequate, accurate, clear, or complete.

117. Merck and Pfizer had a continuing duty to warn the prescribers and users of VIOXX® and CELEBREX® of the dangers associated with said drugs, and breached that duty.

118. The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey and for which Merck and Pfizer are legally responsible.

COUNT IV – FRAUD AND FALSE ADVERTISING
(Against Merck and Pfizer)

119. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

120. Merck and Pfizer owed a duty to provide complete and accurate information regarding VIOXX® and CELEBREX® to Mary McCluskey, prescribers, and anyone else it knew or should have known would ingest, prescribe or recommend the ingestion of said drugs.

121. Merck and Pfizer misrepresented material facts regarding the safety and efficacy of VIOXX® and CELEBREX® and failed to inform and did conceal these material facts from Mary McCluskey, prescribers and the general public.

122. Merck and Pfizer fraudulently, intentionally and/or with gross negligence and recklessness misrepresented to Mary McCluskey, prescribers, and the general public that VIOXX® and CELEBREX® were safe and effective, that the benefits of taking said drugs outweighed any risks, and/or fraudulently, intentionally and/or in a grossly negligent and reckless manner misrepresented and concealed safety and effectiveness

information regarding said drugs, including but not limited to the propensity of said drugs to cause serious physical harm.

123. The continuous and ongoing course of action constituting fraud and misrepresentation on Mary McCluskey, prescribers, and the general public started as early as 1999, if not earlier, and continued through repeated acts and non-disclosure every year since then, throughout the United States and elsewhere.

124. VIOXX® and CELEBREX® were in fact unsafe and their use posed a risk of injury and death which outweighed the purported benefits of such use, thereby causing injury and/or death to Mary McCluskey and others.

125. Merck and Pfizer made misrepresentations and actively concealed adverse information at a time when Merck and Pfizer knew, or should have known, that VIOXX® and CELEBREX® had defects, dangers, and characteristics that were other than what Merck and Pfizer had represented to the prescribing health care providers or other dispensing entities, the FDA, and the consuming public, including Mary McCluskey.

126. Specific misrepresentations and/or active concealment by Merck and Pfizer include, but are not limited to, the following:

c. Failure to disclose that there had been insufficient studies regarding the safety and efficacy of VIOXX® and CELEBREX®;

d. Marketing, promoting and/or selling VIOXX® and CELEBREX® as if they were fully and adequately tested, when they were not;

e. Misrepresenting the safety and efficacy of VIOXX® and CELEBREX® in the labeling, advertising, product inserts, promotional materials, and/or other marketing and/or safety surveillance efforts;

Exhibit A-Part 1

f. Misrepresenting the existence and adequacy of testing of VIOXX® and CELEBREX® both pre-and post-marketing; and

g. Concealing or failing to disclose the severity and frequency of adverse health effects caused by VIOXX® and CELEBREX®.

127. The misrepresentations and/or active concealment alleged above were perpetuated directly and/or indirectly by Merck and Pfizer, and those acting on their behalf.

128. The fraudulent misrepresentations of Merck and Pfizer took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about VIOXX® and CELEBREX®, failure to disclose important safety and injury information regarding said drugs, and elaborate marketing, promotional, and advertising activities designed to conceal and mislead regarding the safety of said drugs, all while having a duty to disclose such information to Mary McCluskey and others.

129. Merck and Pfizer knew or should have known that these representations were false and material at the time they were made or omitted or concealed, and made the representations with the intent or purpose that patients, including Mary McCluskey, and her health care providers would rely on them, leading to the use of VIOXX® and CELEBREX® by such patients, including Mary McCluskey.

130. Mary McCluskey had no knowledge of the information concealed and/or suppressed by Merck and Pfizer.

131. Mary McCluskey was misled and/or relied on and/or was induced by the misrepresentations and/or active concealment by Merck and Pfizer, and was misled and

relied on the absence of safety information which Merck and Pfizer did suppress, conceal or fail to disclose thereby causing injury, damage and/or death to Mary McCluskey.

132. Merck and Pfizer made the misrepresentations and/or actively concealed information with the intention and specific desire that Mary McCluskey and the general public would rely on such misrepresentations or on the absence of information concealed by Merck and Pfizer in selecting and using VIOXX® and CELEBREX®.

133. Merck and Pfizer undertook marketing strategies which included advertising campaigns to aggressively promote and sell VIOXX® and CELEBREX® by misleading and failing to warn potential users about the serious health effects that Merck and Pfizer knew, or should have known, could result from the use of said drugs.

134. This advertising campaign on the whole, through its affirmative misrepresentations and omissions, falsely and fraudulently created the impression that the use of VIOXX® and CELEBREX® were safe and had fewer adverse health and side effects than were actually known to Merck and Pfizer at the time they made these representations.

135. The misrepresentations and/or active concealment by Merck and Pfizer constitute a continuing tort.

136. The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey and for which Merck and Pfizer are legally responsible.

Exhibit A-Part 1

COUNT V - MISREPRESENTATION BY SELLER OF CHATTEL

(Against Merck and Pfizer)

Restatement of Torts (Second) § 402B
or
Restatement of Torts (Third): Prod. Liab. § 9

137. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

138. At all relevant times herein, Merck and Pfizer were in the business of selling prescription drugs, including VIOXX® and CELEBREX®.

139. Through their actions and omissions in advertising, labeling, promotional literature, moving pictures, product brochures, and otherwise, Merck and Pfizer made public misrepresentations of material fact concerning the character, safety, and effectiveness of VIOXX® and CELEBREX® to both the general public and treating and prescribing health care providers.

140. These public misrepresentations and representations include, but are not limited to those set forth in other Counts of this Complaint.

141. The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey and for which Merck and Pfizer are legally responsible.

COUNT VI - BREACH OF EXPRESS AND IMPLIED WARRANTY
(Against Merck and Pfizer)

142. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

Exhibit A-Part 1

143. Merck and Pfizer, through description, affirmation of fact, and promises relating to VIOXX® and CELEBREX®, and made to the FDA, to prescribers, and to the general public, including Mary McCluskey, expressly warranted that VIOXX® and CELEBREX® were both effective and safe for their intended use.

144. These warranties came in the form of:

a. publicly-made written and verbal assurances of the safety and efficacy of VIOXX® and CELEBREX® by Merck and Pfizer;

b. press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for VIOXX® and CELEBREX®, and which failed utterly to warn of the risks inherent to the ingestion and use of said drugs;

c. verbal assurances made by Merck and Pfizer, or their agents, regarding VIOXX® and CELEBREX®, and the downplaying of any risk associated with said drugs;

d. false and misleading written information, supplied by Merck and Pfizer, and published in the *Physicians Desk Reference* on an annual basis, upon which health care providers relied in prescribing VIOXX® and CELEBREX® during the period of Mary McCluskey's ingestion of said drugs;

e. promotional pamphlets and brochures published and distributed by Merck and Pfizer, and directed to consumers; and advertisements.

The documents referred to in this paragraph were created by and at the direction of Merck and Pfizer, and, therefore, are in their possession and control.

145. Merck and Pfizer also impliedly warranted that VIOXX® and CELEBREX® were of merchantable quality and were fit for their intended use and particular purpose.

Exhibit A-Part 1

146. At the time of these express and implied warranties, Merck and Pfizer had knowledge of the purpose for which VIOXX® and CELEBREX® were to be used and warranted said drugs to be in all aspects safe, effective, and proper for such purpose.

147. VIOXX® and CELEBREX® did not conform to these express and implied warranties in that they are neither safe nor effective and their use produces serious adverse side effects, and as such, were not in conformity with the promises, descriptions or affirmations of fact made about said drugs nor were they adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.

148. Merck and Pfizer further breached express and implied warranties to Mary McCluskey by: (i) manufacturing, marketing, packaging, labeling, and selling VIOXX® and CELEBREX® in a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks to Mary McCluskey or prescribing health care providers or pharmacists, and without modifying or excluding such express and implied warranties; and (ii) manufacturing, marketing, packaging, labeling, and selling VIOXX® and CELEBREX® to Mary McCluskey which caused serious physical injury, pain and suffering and/or death.

149. The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey and for which Merck and Pfizer are legally responsible.

COUNT VII – WRONGFUL DEATH

150. Plaintiff repeats and realleges each of the allegations contained in the Complaint as if fully set forth herein.

Exhibit A-Part 1

151. Plaintiff brings this claim on his behalf and on behalf of Mary McCluskey, deceased.

152. As a direct and proximate result of the conduct of Defendants and/or the defective nature of VIOXX®, Mary McCluskey suffered bodily injury and resulting pain and anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses of hospitalization, medical nursing care and treatment, loss of earnings, loss of ability to earn money, and premature death.

153. As a direct and proximate result of Defendants' wrongful conduct, Mary McCluskey incurred hospital, nursing, and medical expenses. Mary McCluskey's beneficiaries have incurred hospital, nursing, medical, funeral and estate administration expenses as a result of her death.

154. By reason of the foregoing, Plaintiff has been damaged by the negligent, wantonness, willfulness and recklessness of these Defendants.

WHEREFORE, the Plaintiff demands a money judgment against Defendants in such an amount as a jury deems reasonable, just and appropriate, and seeks interest and the costs of these proceedings.

COUNT VIII – CONSUMER PROTECTION ACT
(Against Merck and Pfizer)

155. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

156. Merck and Pfizer misrepresented the efficacy and safety of VIOXX® and CELEBREX® to Mary McCluskeys through their advertising, promotion and sales efforts, as directed to Mary McCluskey, the local community, prescribing health care providers and the FDA.

Exhibit A-Part 1

157. Merck and Pfizer's actions and failures to act as alleged in this Complaint constitute unfair, false, misleading and deceptive acts and practices in the conduct of trade and commerce in violation of the Alabama Consumer Protection Act.

158. As a result of Merck and Pfizer's deceptive and unconscionable conduct, Mary McCluskey was prescribed VIOXX® and CELEBREX®, Mary McCluskey purchased VIOXX® and CELEBREX® and Mary McCluskey did in fact consume VIOXX® and CELEBREX®. Mary McCluskey's use of VIOXX® and CELEBREX® was entirely for Mary McCluskey's personal purposes.

159. Mary McCluskey is within the class of people intended to be protected by the Alabama Consumer Protection Act.

160. The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey and for which Merck and Pfizer are legally responsible.

161. 157. In addition, the Court should award Plaintiff reasonable attorneys' fees and costs as allowed by the Alabama Consumer Protection Act.

COUNT IX
(Claims against James A. Stewart, Anna Leigh Webb, Cedric D. Anderson, Travis Taylor and Robert Vandelune Sales Representative Defendants)

162. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

163. At all times material hereto, the Defendants, John Doe One and John Doe Two (hereinafter called the "Sales Representative Defendants") as employees of Merck and Pfizer were in the business of marketing and promoting the pharmaceutical drugs VIOXX® and CELEBREX® within the State of Alabama.

Exhibit A-Part 1

164. As set forth more completely herein, the Sales Representative Defendants owed various duties to Mary McCluskey, but breached those duties by committing positive tortious actions including but not limited to their interactions and misrepresentations to Mary McCluskey's prescribing health care provider(s) regarding VIOXX® and CELEBREX®.

165. The Sales Representative Defendants owed a duty to provide complete and accurate information regarding VIOXX® and CELEBREX® to Mary McCluskey's health care provider(s), and anyone else they knew or should have known would ingest, prescribe or recommend the ingestion of VIOXX® and CELEBREX®.

166. The Sales Representative Defendants misrepresented material facts regarding the safety and efficacy of VIOXX® and CELEBREX®, and failed to inform and did conceal from Mary McCluskey, the public and health care providers these material facts. The Sales Representative Defendants also supplied Mary McCluskey's health care provider(s) with labeling information supplied by the manufacturer when they knew or should have known that the labeling information that was supplied with VIOXX® and CELEBREX® was inaccurate, misleading and incomplete.

167. The Sales Representative Defendants fraudulently, intentionally and/or with gross negligence and recklessness misrepresented to Mary McCluskey's health care provider(s), and the general public that VIOXX® and CELEBREX® were safe and effective, that the benefits of taking the drugs outweighed any risks, and/or fraudulently, intentionally and/or in a grossly negligent and reckless manner misrepresented and concealed safety and effectiveness information regarding VIOXX® and CELEBREX®,

Exhibit A-Part 1

including but not limited to the propensity of VIOXX® and CELEBREX® to cause serious physical harm.

168. VIOXX® and CELEBREX® were in fact unsafe and the use of them posed a risk of injury and death which outweighed the purported benefits from such use, such that injury was in fact caused to Mary McCluskey and others.

169. The Sales Representative Defendants made misrepresentations and actively concealed adverse information at a time when they knew, or should have known, that VIOXX® and CELEBREX® had defects, dangers, and characteristics that were other than what had been represented to the prescribing health care provider(s) or other dispensing entities, the FDA, and the consuming public, including Mary McCluskey.

170. The Sales Representative Defendants knew, or should have known, or consciously or recklessly chose not to know, that these representations were false and material at the time they were made or omitted or concealed, and made the representations with the intent or purpose that Mary McCluskey's health care provider(s) would rely on them, leading to the use of VIOXX® and CELEBREX® by Mary McCluskey.

171. The Sales Representative Defendants made the misrepresentations and/or actively concealed this information with the intention and specific desire that Mary McCluskey's health care provider(s) or other dispensing entities and the consuming public would rely on such or the absence of information in selecting VIOXX® and CELEBREX® as a treatment for Mary McCluskey.

172. Mary McCluskey's health care provider(s) relied on and/or were induced by the misrepresentations and/or active concealment and on the absence of safety

information which the Sales Representative Defendants did suppress, conceal or fail to disclose.

173. The misrepresentations of and/or active concealment by the Sales Representative Defendants constitute a continuing tort.

174. The tortious acts by the Sales Representative Defendants include, but are not limited to, the following:

a. The Sales Representative Defendants were in the business of marketing, promoting, selling and/or distributing the unreasonably dangerous drugs, VIOXX® and CELEBREX®, which caused harm to Mary McCluskey;

b. The Sales Representative Defendants negligently distributed, marketed, advertised and/or promoted the dangerous drugs VIOXX® and CELEBREX®;

c. The Sales Representative Defendants failed to adequately warn prescribing health care providers of the dangers VIOXX® and CELEBREX® posed and failed to discuss the lack of efficacy of the drugs;

d. The Sales Representative Defendants made negligent and/or intentional misrepresentations regarding the safety and efficacy of the dangerous drugs, VIOXX® and CELEBREX®.

175. The Sales Representative Defendants were directly involved in selling the defective products VIOXX® and CELEBREX® to Mary McCluskey in that they each made visits to the office of Mary McCluskey's prescribing health care provider(s), specifically intending to cause said health care provider(s) to prescribe VIOXX® and CELEBREX®.

176. The Sales Representative Defendants detailed the health care provider(s) who prescribed VIOXX® and CELEBREX® for Mary McCluskey, and during such detailing encouraged the use of VIOXX® and CELEBREX® in situations where such use was not indicated, and/or gave the health care provider(s) a copy of an article or

articles which reported favorably on the safety of VIOXX® and CELEBREX®. The Sales Representative Defendants understated or misrepresented associated risks and/or overstated the safety and effectiveness of the drugs, and/or provided materially incomplete information in those respects.

177 The Sales Representative Defendants knew that it was wrongful to understate or withhold information regarding the risks of VIOXX® and CELEBREX® and to overstate their safety and effectiveness, or to make representations to health care providers that were not based on complete information.

178. The Sales Representative Defendants had knowledge of the circumstances, of their duties, and of the actionable wrongs set out herein – such as the over-promotion of VIOXX® and CELEBREX® and misrepresentations and omissions – but nonetheless participated in and/or contributed to the commission of the wrongdoing.

179. The Sales Representative Defendants developed a professional relationship with Mary McCluskey's prescribing health care provider(s).

180. Part of that relationship involved the Sales Representative Defendants providing information to Mary McCluskey's prescribing health care provider(s) about VIOXX® and CELEBREX®.

181. Mary McCluskey's prescribing health care provider(s) relied upon the information provided by the Sales Representative Defendants.

182. Having developed this relationship with Mary McCluskey's prescribing health care provider(s), the Sales Representative Defendants owed a duty to Mary McCluskey's prescribing health care provider(s) and consequently to the patients of said health care provider(s) to provide adequate warnings about VIOXX® and CELEBREX®.

Exhibit A-Part 1

183. Further, by this relationship, the Sales Representative Defendants owed a duty to Mary McCluskey's prescribing health care provider(s) not to exaggerate the efficacy or minimize the risk of VIOXX® and CELEBREX®.

184. As a direct result of the efforts of the Sales Representative Defendants, Mary McCluskey's prescribing health care provider(s) prescribed VIOXX® and CELEBREX® to Mary McCluskey.

185. The Sales Representative Defendants breached their duty to Mary McCluskey, as a foreseeable ultimate consumer of the product being sold, in that:

a. They knew or should have known of the cardiovascular risks associated with VIOXX® and CELEBREX®, alleged above, but did not adequately inform Mary McCluskey's prescribing health care provider(s);

b. They knew or should have known that VIOXX® and CELEBREX® were not reasonably safe but did not tell Mary McCluskey's prescribing health care provider(s); and,

c. They failed to adequately stress the limited efficacy of VIOXX® and CELEBREX®, while simultaneously over-stating the safety of the drugs and misrepresenting their safety profile.

186. The Sales Representative Defendants breached their duties alleged above and such breach constituted a foreseeable and substantial factor contributing to Mary McCluskey's injuries and death.

187. The Sales Representative Defendants made the misrepresentations set forth in this Count either knowing that they were untrue or recklessly without regard for the truth or falsity of such representations.

188. The misrepresentations of and/or active concealment alleged above were perpetuated directly and/or indirectly by the Sales Representative Defendants, acting in both their individual and corporate capacity.

Exhibit A-Part 1

189. The actions set forth in this Count were a substantial factor in causing damages, as set out in the Counts below, to Mary McCluskey, and for which the Sales Representative Defendants are legally responsible.

COUNT X –DAMAGES
(Against All Defendants)

190. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

191. As a result of the actions and failures to act of Merck, Pfizer, John Doe One and John Doe Two, as set forth in this Complaint, Mary McCluskey did sustain injuries and resulting death.

192. As a result of the actions and failures to act of Merck, Pfizer, John Doe One and John Doe Two as set forth in this Complaint, Mary McCluskey has incurred, and will in the future incur, medical and other expenses for Mary McCluskey's care, rehabilitation and treatment, including the expense of hospitalization, nursing care and other treatments.

193. As a result of the actions and failures to act of Merck, Pfizer, John Doe One and John Doe Two as set forth in this Complaint, Mary McCluskey or those on her behalf have incurred medical and hospital expenses, funeral and administration expenses, loss of earning capacity, shortened life expectancy and loss of enjoyment of life. Her loves ones also lost the love and affection of having Mary McCluskey in their lives.

194. Merck, Pfizer, John Doe One and John Doe Two are jointly and severally liable for the compensatory damages Mary McCluskey has set forth herein.

Exhibit A-Part 1

COUNT XI - PUNITIVE DAMAGES
(Against Merck and Pfizer)

195. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

196. Plaintiff is entitled to punitive damages because Merck and Pfizer's actions and failure to act as set forth herein were reckless and without regard for the public's safety and welfare. Merck and Pfizer misled both the medical community and the public at large, including decedent Mary McCluskey by making false representations about the safety of VIOXX® and CELEBREX®. Merck and Pfizer downplayed, understated and disregarded their knowledge of the serious adverse events and side effects associated with the use of VIOXX® and CELEBREX®, despite available information demonstrating that VIOXX® and CELEBREX® were likely to cause serious and sometimes fatal side effects to users.

197. Merck and Pfizer were or should have been in possession of evidence demonstrating that VIOXX® and CELEBREX® caused serious adverse events and side effects. Merck and Pfizer failed to conduct appropriate and necessary testing, despite repeated indications and calls therefore, and continued to market VIOXX® and CELEBREX® by providing false and misleading information with regard to the safety and efficacy of said drugs.

198. Merck and Pfizer acted willfully, wantonly, intentionally, outrageously, maliciously and with reckless and conscious disregard for the health, welfare, safety and rights of decedent and the general public.

199. Merck and Pfizer are liable to Mary McCluskey and for punitive damages in an amount as supported by the evidence and the law of the State of Alabama.

Exhibit A-Part 1

COUNT XII - LOSS OF CONSORTIUM
(Against All Defendants)

200. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.

201. As a result of the actions and failures to act of Merck, Pfizer, John Doe One and John Doe Two as set forth in this Complaint, Plaintiff William McCluskey has incurred medical, funeral and other expenses.

202. As a result of the actions and failures to act of Merck, Pfizer, John Doe One and John Doe Two as set forth in this Complaint, Plaintiff William McCluskey has suffered the loss of decedent Mary McCluskey's affection, companionship, services and society, and the marital association between husband and wife has been impaired and depreciated, as a result of which Plaintiff William McCluskey has been and will be caused great suffering, loss and mental anguish.

203. Merck, Pfizer, John Doe One and John Doe Two are jointly and severally liable for the compensatory damages of Plaintiff William McCluskey as set forth herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff William D. McCluskey, request that this Court enter judgment against Defendants, and award relief as follows:

i. Compensatory damages against Merck & Co., Inc., Pfizer, Inc., John Doe One and John Doe Two, jointly and severally, in an amount supported by the evidence at trial;

ii. An award of attorneys' fees, pre-judgment and post-judgment interest, and costs of suit, as provided by law against Merck & Co., Inc., Pfizer, Inc., John Doe One and John Doe Two, jointly and severally;

Exhibit A-Part 1